

1 JORDAN RAPHAEL (SBN 252344)
jraphael@byronraphael.com
2 BYRON RAPHAEL LLP
1055 West 7th Street, Suite 3300
3 Los Angeles, CA 90017
Telephone: (213) 291-9800
4 Facsimile: (213) 377-5771

5 DENNIS A. HENIGAN (Of Counsel)
dhenigan@tobaccofreekids.org
6 SWATI RAWANI (Of Counsel)
srawani@tobaccofreekids.org
7 1400 I Street, NW, Suite 1200
Washington, D.C. 20005
8 (202) 296-5469

9 Counsel for *Amici Curiae*

10 **IN THE UNITED STATES DISTRICT COURT**
11 **FOR THE SOUTHERN DISTRICT OF CALIFORNIA**

12 R.J. REYNOLDS TOBACCO
13 COMPANY; R.J. REYNOLDS VAPOR
14 COMPANY; and SANTA FE NATURAL
TOBACCO COMPANY, INC.,

15 Plaintiffs,

16 v.

17 COUNTY OF SAN DIEGO and HELEN
18 N. ROBBINS-MEYER, in her official
capacity as the County of San Diego
Chief Administrative Officer,

19 Defendants.
20

) No. 20-cv-01290-JLS-WVG

) **BRIEF OF *AMICI CURIAE* IN**
) **OPPOSITION TO PLAINTIFFS'**
) **MOTION FOR PRELIMINARY**
) **INJUNCTION**

) Hearing Date: September 24, 2020

) Time: 1:30 PM

) Courtroom: 4D

) Judge: Janis L. Sammartino

) Magistrate: William V. Gallo

) Action Filed: July 9, 2020

) Trial Date: None Set

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Cases

CA Smoke & Vape Ass’n v. County of Los Angeles, et al.,
CV 20-4065, 2020 WL 4390384 (C.D. Cal. June 9, 2020)..... 4

Indep. Gas & Serv. Stations Ass’ns., Inc. v. City of Chicago,
112 F.Supp.3d 749 (N.D. Ill. 2015)..... 4

Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence, R.I.,
731 F.3d 71 (1st Cir. 2013) 4

Nicopure Labs LLC v. FDA,
944 F.3d 266 (D.C. Cir. 2019) 8

R.J. Reynolds Tobacco Co. v. County of Los Angeles,
CV 20-4880, 2020 WL 4390375 (C.D. Cal. July 13, 2020) 4

U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York,
708 F.3d 428 (2d. Cir. 2013)..... 4, 5

Regulations

Deeming Tobacco Products To Be Subject to the Federal Food, Drug,
and Cosmetic Act, as Amended by the Family Smoking Prevention
Tobacco Control Act; Restrictions on the Sale and Distribution of
Tobacco Products and Required Warning Statements for Tobacco
Products,
81 Fed. Reg. 28,974 (May 20, 2016) (to be codified at 21 C.F.R. pt.
1100, 1140, 1143)..... 11, 16, 17

Regulation of Flavors in Tobacco Products,
83 Fed. Reg. 12,294 (proposed Mar. 21, 2018) (to be codified at 21
C.F.R. pt. 1100, 1140, 1143) passim

Other Authorities

Alexa R. Romberg, et al.,
*Patterns of Nicotine Concentrations in Electronic Cigarettes Sold
in the United States, 2013-2018*, 203 Drug and Alcohol
Dependence 1 (2019)..... 10

Allen Hackshaw, et al.,
Low cigarette consumption and risk of coronary heart disease and

1 *stroke: meta-analysis of 141 cohort studies in 55 study reports*, 360
 2 *BMJ* j5855 (2018)..... 10

3 Andrea Villanti, et al.,
 4 *Changes in the Prevalence and Correlates of Menthol Cigarette*
 5 *Use in the USA, 2004–2014*, 25 *Tobacco Control* ii14 (2016) 12

6 Brian King, Am. Lung Ass’n,
 7 Webinar, *Update with CDC for Chronic Disease Partners on*
 8 *COVID-19* (Apr. 17, 2020)..... 13

9 Bridget K. Ambrose, et al.,
 10 *Flavored Tobacco Product Use Among US Youth Aged 12-17*
 11 *Years, 2013-2014*, 314 *J. Am. Med. Ass’n* 17 (2015)..... 2

12 Campaign for Tobacco-Free Kids,
 13 *States & Localities That Have Restricted the Sale of Flavored*
 14 *Tobacco Products* (Aug. 5, 2020) 10

15 CDC,
 16 *About Electronic Cigarettes (E-Cigarettes)* 10

17 CDC,
 18 *Behavioral Risk Factor Surveillance System, Prevalence and*
 19 *Trends, E-Cigarette Use* (2017)..... 6

20 CDC,
 21 *COVID-19 in Racial and Ethnic Minority Groups* (2020)..... 15

22 CDC,
 23 *QuickStats: Cigarette Smoking Status Among Current Adult E-*
 24 *cigarette Users, by Age Group — National Health Interview*
 25 *Survey, United States, 2015*, 65 *Morbidity & Mortality Wkly. Rep.*
 26 1177 (2016)..... 10

27 CDC,
 28 *Tobacco Product Use and Associated Factors Among Middle and*
 High School Students—United States, 2019, 68 *Morbidity &*
 Mortality Wkly. Rep. Surveillance Summaries, Dec. 6, 2019..... 3, 6

 CDC,
 Use of Electronic Cigarettes and Any Tobacco Product Among
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 Morbidity & Mortality Wkly. Rep. 1276 (2018) 6

1 FDA,
 2 *Modifications to Compliance Policy for Certain Deemed Products:*
 3 *Guidance for Industry, Draft Guidance* (2019)3, 7
 4 Ganna Kostygina, et al.,
 5 *Tobacco Industry use of Flavours to Recruit New Users of Little*
 6 *Cigars and Cigarillos*, 25 *Tobacco Control* 66 (2016) 16
 7 Greta Zhu, et al.,
 8 *Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-*
 9 *2017: Analysis of Brand Websites*, 20 *J. Med. Internet Res.* e80
 10 (2018)..... 7
 11 Jessica L. Barrington-Trimis, et al.,
 12 *Flavorings in Electronic Cigarettes: An Unrecognized Respiratory*
 13 *Health Hazard?*, 312 *J. Am. Med. Ass’n* 2493 (2014) 8
 14 Kaitlin M. Berry, et al.,
 15 *Association of Electronic Cigarette Use with Subsequent Initiation*
 16 *of Tobacco Cigarettes in U.S. Youths*, 2 *J. Am. Med. Ass’n*
 17 *Network Open* e187794 (2019)9
 18 Kjell Bjartveit & Aage Tverdal,
 19 *Health Consequences of Smoking 1-4 Cigarettes per Day*, 14
 20 *Tobacco Control* 315 (2005) 10
 21 Lisa Henriksen, et al.,
 22 *Targeted Advertising, Promotion, and Price for Menthol Cigarettes*
 23 *in California High School Neighborhoods*, 14 *Nicotine Tobacco*
 24 *Rsch.* 116 (2012)..... 14
 25 M. Niksic,
 26 *Flavored Smokes: Mmmm...More Profits?*, *Tobacco Retailer*,
 27 *Apr. 2007*..... 16
 28 NASEM,
Public Health Consequences of E-cigarettes (2018)9, 10
 Nina Schleicher, et al., *California Tobacco Retail Surveillance Study,*
2018, Stanford Prevention Research Center (2019)..... 14
 Nora Volkow,
Potential Implications for Individuals with Substance Use
Disorders, NIDA: Nora's Blog (Apr. 6, 2020)..... 3

1 Office of the Surgeon General, HHS,
 2 *Cardiovascular System, in How Tobacco Smoke Causes Disease:
 3 The Biology and Behavioral Basis for Smoking-Attributable
 4 Disease: A Report of the Surgeon General* (2010) 8
 5 Office of the Surgeon General, HHS,
 6 *E-Cigarette Use Among Youth and Young Adults, A Report of the
 7 Surgeon General* (2016) 8
 8 Office of the Surgeon General, HHS,
 9 *The Health Consequences of Smoking - 50 Years of Progress: A
 10 Report of the Surgeon General* (2014) 2, 7
 11 Office of the Surgeon General, HHS,
 12 *The Health Consequences of Smoking: A Report of the Surgeon
 13 General* (2004) 10
 14 Office of the Surgeon General, HHS,
 15 *Preventing Tobacco Use Among Youth and Young Adults, A Report
 16 of the Surgeon General* (2012) 7
 17 Office of the Surgeon General, HHS,
 18 *Smoking Cessation, A Report of the Surgeon General* (2020) 7, 11, 14
 19 Office of the Surgeon General, HHS,
 20 *Surgeon General’s Advisory on E-Cigarette Use Among Youth
 21 (2018)* 6, 7, 8
 22 Office on Smoking and Health, CDC,
 23 *Electronic Nicotine Delivery Systems: Key Facts* (2016) 7
 24 Reis Thebault, et al.,
 25 *The coronavirus is infecting and killing black Americans at an
 26 alarmingly high rate*, Washington Post (Apr. 7, 2020) 15
 27 Richard Miech, et al.,
 28 *Trends in Adolescent Vaping, 2017-2019*, 381 *New Eng. J. Med.*
 1490 (2019) 6
 SAMHSA, HHS,
2018 National Survey on Drug Use and Health (2019) 16
 SAMHSA, HHS,
National Survey on Drug Use and Health (2014) 2

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Shu-Hong Zhu, et al.,
Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation, 23 *Tobacco Control* iii3 (2014).....7

Tobacco Products Scientific Advisory Committee, FDA,
Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations (2011)12, 13, 14, 15

World Health Organization,
Tobacco Use and COVID-19 (May 11, 2020)13

1 *Amici* public health, medical and community organizations submit this brief
2 in opposition to plaintiffs’ motion for preliminary injunction to prevent
3 enforcement of an ordinance to prohibit the sale of flavored tobacco products and to
4 temporarily suspend the sale of e-cigarettes in the County of San Diego (the
5 “Flavors Ordinance”).

6 **STATEMENT OF INTEREST OF AMICI CURIAE**

7 *Amici* here include the following national, state, and local public health,
8 medical and community organizations: African American Tobacco Control
9 Leadership Council, American Academy of Pediatrics California, American Cancer
10 Society Cancer Action Network, American Heart Association, American Lung
11 Association, American Medical Association, Americans for Nonsmokers’ Rights,
12 California School Nurses Organization, Campaign for Tobacco-Free Kids, Parents
13 Against Vaping e-cigarettes, Public Health Law Center and Truth Initiative.

14 As is evident from the description of the *amici* included in the Appendix to
15 this brief, each of these groups works, on a daily basis, to reduce the devastating
16 health harms of tobacco products. From pediatricians who counsel their young
17 patients and their parents about the hazards of tobacco use, to organizations with
18 formal programs to urge users to quit, to groups representing parents and families
19 struggling to free young people from nicotine addiction, each of these organizations
20 has a direct and immediate interest in curbing the sale of flavored tobacco products,
21 as well as substantial expertise in the role those products play in enticing young
22 people to tobacco use. An injunction preventing enforcement of the Flavors
23 Ordinance in San Diego County would undercut the efforts of these organizations
24 to curb tobacco use, particularly among the young. The *amici* are particularly well
25 suited to inform the Court of the full range of community health harms that an
26 injunction would cause, thus providing the Court with the most complete
27 information needed for a fair balancing of the hardships in this case and an accurate
28 assessment of the effect of an injunction on the public interest.

INTRODUCTION

1 The use of tobacco products is the leading cause of preventable death in the
 2 United States, taking upwards of 480,000 lives every year.¹ The tobacco industry
 3 has long understood that almost all new tobacco users begin their addiction as kids.
 4 Ninety percent of adult smokers begin smoking in their teens.² The industry has
 5 also known that to successfully market their products to young people, flavored
 6 products are essential. No matter what the tobacco product – from cigarettes to
 7 cigars to smokeless tobacco to e-cigarettes to hookah -- flavors significantly
 8 increase the appeal of tobacco products to youth. Data from the U.S. Food and Drug
 9 Administration (FDA)/NIH Population Assessment of Tobacco and Health (PATH)
 10 study found that almost 81% of 12-17 year-olds who had ever used a tobacco
 11 product initiated use with a flavored product.³ For each tobacco product, at least
 12 two-thirds of youth reported using these products “because they come in flavors I
 13 like.”⁴ As the FDA has found, “the availability of tobacco products with flavors at
 14 these developmental stages attracts youth to initiate use of tobacco products and
 15 may result in lifelong use.”⁵ Indeed, flavored e-cigarettes have fueled an explosion
 16 of e-cigarette use among teens. Among high school students, e-cigarette use more
 17 than doubled from 2017 to 2019, increasing from 11.7% to 27.5%. Over 5.3 million
 18 youth were current e-cigarette users in 2019 – a remarkable increase of over 3
 19

21 _____
 22 ¹ Office of the Surgeon General (OSG), U.S. Department of Health and
 23 Human Services (HHS), *The Health Consequences of Smoking - 50 Years of*
 24 *Progress: A Report of the Surgeon General 2* (2014),
 25 <https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf>.

26 ² Substance Abuse and Mental Health Services Administration (SAMHSA),
 27 HHS, *National Survey on Drug Use and Health* (2014),
 28 <http://doi.org/10.3886/ICPSR36361.v1>.

³ Bridget K. Ambrose, et al., *Flavored Tobacco Product Use Among US*
Youth Aged 12-17 Years, 2013-2014, 314 J. Am. Med. Ass’n 17, 1871-3 (2015),
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6467270/>.

⁴ *Id.*

⁵ Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294, 12,295
 (proposed Mar. 21, 2018) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143)
 (“Advance Notice of Proposed Rulemaking”)

1 million students since 2017.⁶ PATH study data shows that 97% of current youth e-
2 cigarette users had used a flavored product in the last month.⁷

3 By enacting the Flavors Ordinance, San Diego County has sought to protect
4 its residents – and particularly its young people – from the continuing and
5 increasing scourge of flavored tobacco products that lure millions into a lifetime of
6 addiction, disease and death. Plaintiffs seek an injunction that would deprive the
7 public of that vital public health protection. Moreover, plaintiffs seek an injunction
8 at a time when our nation is ravaged by the horrific spread of the novel coronavirus
9 and COVID-19 -- a deadly respiratory illness that has taken tens of thousands of
10 lives, while paralyzing daily life. Dr. Nora Volkow, Director of the U.S. National
11 Institute on Drug Abuse, has observed that “[b]ecause it attacks the lungs, the
12 coronavirus that causes COVID-19 could be an especially serious threat to those
13 who smoke tobacco or marijuana or who vape”⁸ Never has it been more
14 important to curb the sale of flavored tobacco products that lure kids to smoking
15 and vaping. Yet the injunction sought by plaintiffs would not only permit the
16 continued sale of flavored e-cigarettes, but also the sale of mentholated cigarettes,
17 flavored cigars and other flavored tobacco products. The County’s brief
18 persuasively demonstrates that plaintiffs have little likelihood of succeeding on the
19 merits of their claims against the Flavors Ordinance. As to federal preemption of
20 local law, the County has shown that the Food, Drug and Cosmetic Act, as
21 amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco
22

23 ⁶ CDC, *Tobacco Product Use and Associated Factors Among Middle and*
24 *High School Students—United States, 2019*, 68 *Morbidity & Mortality Wkly. Rep.*
Surveillance Summaries, Dec. 6, 2019,
25 <https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf>.

26 ⁷ FDA, *Modifications to Compliance Policy for Certain Deemed Products:*
Guidance for Industry, Draft Guidance, at 9 (Mar. 13, 2019),
<https://beta.regulations.gov/document/FDA-2019-D-0661-0003>.

27 ⁸ Nora Volkow, *Potential Implications for Individuals with Substance Use*
28 *Disorders*, NIDA: Nora's Blog (Apr. 6, 2020), <https://www.drugabuse.gov/about-nida/noras-blog/2020/04/covid-19-potential-implications-individuals-substance-use-disorders>.

1 Control Act) confers authority on the FDA to regulate the manufacture of tobacco
2 products through the issuance of product standards, while expressly preserving to
3 states and localities their traditional broad authority to protect the health of their
4 citizens by regulating the retail sale of finished tobacco products. Most recently,
5 federal preemption challenges virtually identical to the one at issue here, one
6 brought by plaintiffs in this action, were rejected in *R.J. Reynolds Tobacco Co. v.*
7 *County of Los Angeles*, No. CV 20-4880, 2020 WL 4390375, at *5 (C.D. Cal. July
8 13, 2020) (order denying plaintiffs’ motion for preliminary injunction) (“A
9 prohibition on the sale of a distinct product is simply not a product standard.”); No.
10 CV 20-4880 (C.D. Cal. Aug. 7, 2020) (order granting defendants’ motion to
11 dismiss and denying plaintiffs’ motion for summary judgment as moot), and in *CA*
12 *Smoke & Vape Ass’n v. County of Los Angeles*, No. CV 20-4065, 2020 WL
13 4390384 (C.D. Cal. June 9, 2020) (order denying plaintiffs’ motion for preliminary
14 injunction); No. CV 20-4065 (C.D. Cal. Aug. 7, 2020) (order granting defendants’
15 motion to dismiss). Indeed, every court that has considered the issue has found that
16 sales restrictions on flavored tobacco products are not preempted by federal law.
17 *See U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 433-
18 35 (2d. Cir. 2013) (upholding local sales restrictions on flavored tobacco products
19 because their application to a particular product “depends on its characteristics as
20 an end product, and not on whether it was manufactured in a particular way or with
21 particular ingredients.”); *Nat’l Ass’n of Tobacco Outlets, Inc. v. City of Providence,*
22 *R.I.*, 731 F.3d 71, 83, n.11 (1st Cir. 2013) (upholding local restrictions on sale of
23 flavored tobacco products, given “Congress’ decision to exempt sales regulations
24 from preemption. . . .”); *Indep. Gas & Serv. Stations Ass’ns., Inc. v. City of*
25 *Chicago*, 112 F.Supp.3d 749, 754 (N.D. Ill. 2015) (upholding Chicago’s flavored
26 tobacco sales restrictions as exempt from Tobacco Control Act preemption
27 provision because Chicago ordinance “regulates flavored tobacco products without
28 regard for how they are manufactured” and is “not a command to implement

1 particular manufacturing standards”). The Flavors Ordinance, because it does not
2 operate as a command to manufacturers limiting how a product is manufactured or
3 what ingredients it may contain, in no way interferes with FDA authority to set
4 product standards. Far from interfering with the federal regulatory scheme, the
5 Flavors Ordinance advances the Tobacco Control Act’s “objective of reducing the
6 use and harmfulness of tobacco products, especially among young people.” *U.S.*
7 *Smokeless Tobacco*, 708 F.3d at 436. Given the County’s thorough demonstration
8 that plaintiffs are unlikely to prevail on the merits of their legal claims, *amici* focus
9 here on other factors to be weighed by the Court in determining whether to grant a
10 preliminary injunction: the balance of the equities and whether an injunction would
11 serve the public interest. Plaintiffs’ claims of irreparable harm are either dependent
12 on the validity of their preemption argument, which has no merit, or the financial
13 loss of being deprived of the ability to continue to sell tobacco products that, as the
14 discussion *infra* shows, cause significant harm to public health. As the *amici* here
15 demonstrate, plaintiffs’ alleged financial harm is far outweighed by the health
16 harms long suffered by the residents of San Diego County due to flavored tobacco
17 products. By this brief, *amici* seek to inform the Court of the scope of harm to
18 public health that would be inflicted by an injunction that would allow the
19 continued sale in this County of flavored tobacco products. Because of that harm,
20 the balance of equities tips decisively against a preliminary injunction and such an
21 injunction would be profoundly contrary to the public interest.

ARGUMENT

I. The Health Harms of Continued Sale of Flavored E-Cigarettes Weigh Significantly Against the Grant Of An Injunction.

A. E-Cigarettes Available in Thousands of Flavors Increase Youth Usage and Pose Serious Health Risks to Youth.

The most dramatic surge in youth usage of flavored tobacco products has occurred with e-cigarettes,⁹ as they have become by far the most commonly used tobacco product among U.S. youth. Whereas the 2019 National Youth Tobacco Survey (NYTS) showed that 5.8% of high school students smoked regular cigarettes, 27.5% used e-cigarettes.¹⁰ In December 2018, Surgeon General Jerome Adams issued an advisory on e-cigarette use among youth, declaring the growing problem an “epidemic.”¹¹

Young people are not just experimenting with e-cigarettes but are using them frequently. More than a third (34.2%) of high school e-cigarette users are frequent users, using e-cigarettes on at least 20 of the preceding 30 days.¹² Alarming, 1 in 9 of all high school seniors (11.7%) report that they vaped nicotine nearly daily, a strong indication of deep addiction.¹³

Tobacco companies have a long history of using flavors to reduce the harshness of their products and make them more appealing to new users, almost all of whom are under age 18.¹⁴ In recent years, companies have extended this strategy

⁹ By “e-cigarettes,” *amici* refer to the full range of “electronic smoking devices” as that term is defined in the Flavors Ordinance.

¹⁰ CDC, *supra* note 6.

¹¹ OSG, HHS, *Surgeon General’s Advisory on E-Cigarette Use Among Youth* (2018), <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>.

¹² CDC, *supra* note 6.

¹³ Richard Miech, et al., *Trends in Adolescent Vaping, 2017-2019*, 381 *New Eng. J. Med.* 1490, 1491 (2019), <https://www.nejm.org/doi/full/10.1056/NEJMc1910739>.

¹⁴ OSG, HHS, *Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General* 483-628 (2012), https://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf_NBK99237.pdf.

1 to the emerging market for e-cigarettes. As of 2017, researchers had identified more
 2 than 15,500 unique e-cigarette flavors available online.¹⁵ An earlier study of e-
 3 cigarette flavors found that among the more than 400 brands available online in
 4 2014, 84% offered fruit flavors and 80% offered candy and dessert flavors.¹⁶ E-
 5 liquids are being sold in such kid-friendly options as cotton candy, peanut butter
 6 cup, and gummy bear. The data confirms that flavors play a major role in youth
 7 initiation and use of e-cigarettes. The 2020 Surgeon General Report on smoking
 8 cessation notes that “the role of flavors in promoting initiation of tobacco product
 9 use among youth is well established . . . and appealing flavor is cited by youth as
 10 one of the main reasons for using e-cigarettes.”¹⁷ As noted above, data from the
 11 2016–17 wave of the government’s PATH study found that 97% of current youth e-
 12 cigarette users had used a flavored e-cigarette in the past month.¹⁸ Flavored e-
 13 cigarettes and refill liquids typically contain nicotine, a highly addictive drug that
 14 can have lasting damaging effects on adolescent brain development.¹⁹ According to
 15 the Surgeon General’s *Advisory on E-cigarette Use Among Youth*, “[n]icotine
 16 exposure during adolescence can impact learning, memory and attention,” and “can
 17 also increase risk for future addiction to other drugs.”²⁰ Nicotine also impacts the
 18 cardiovascular system.²¹ The Surgeon General has warned that, “[t]he use of

19
 20 ¹⁵ Greta Zhu, et al., *Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites*, 20 *J. Med. Internet Res.* e80 (2018), <https://www.jmir.org/2018/3/e80/>.

21 ¹⁶ Shu-Hong Zhu, et al., *Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation*, 23 *Tobacco Control* iii3 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4078673/>.

22 ¹⁷ OSG, HHS, *Smoking Cessation, A Report of the Surgeon General*, at 611 (2020), <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.

23 ¹⁸ FDA, *supra* note 7.

24 ¹⁹ OSG, *supra* note 1; see also Office on Smoking and Health, CDC, *Electronic Nicotine Delivery Systems: Key Facts* (2016), <https://www.cdc.gov/tobacco/stateandcommunity/pdfs/ends-key-facts-oct-2016.pdf>.

25 ²⁰ OSG, *supra* note 11, at 1.

26 ²¹ OSG, HHS, *Cardiovascular System*, in *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General* (2010), <https://www.ncbi.nlm.nih.gov/books/NBK53012/>.

1 products containing nicotine in any form among youth, including in e-cigarettes, is
2 unsafe.”²² Flavorings in e-cigarettes can pose additional health hazards. According
3 to the Surgeon General, some of the flavorings found in e-cigarettes have been
4 shown to cause serious lung disease when inhaled.²³ An article in the Journal of the
5 American Medical Association raised concerns that the chemical flavorings found
6 in some e-cigarettes and e-liquids could cause respiratory damage when the e-
7 cigarette aerosol is inhaled deeply into the lungs.²⁴ In *Nicopure Labs LLC v. FDA*,
8 the U.S. Court of Appeals for the D.C. Circuit relied on findings that flavors in e-
9 cigarettes are harmful in upholding the application of FDA’s premarket review
10 process to e-cigarettes. *See* 944 F.3d 266 (D.C. Cir. 2019). Specifically, the court
11 found that:

12 Aldehydes, “a class of chemicals that can cause respiratory irritation”
13 and “airway constriction,” appear in many flavored e-cigarettes,
14 including cotton candy and bubble gum. One study found that the
15 flavors “dark chocolate” and “wild cherry” exposed e-cigarette users to
16 more than twice the recommended workplace safety limit for two
different aldehydes. Like secondary smoke inhalation from
conventional cigarettes, exhaled aerosol from e-cigarettes may include
nicotine and other toxicants that can pose risks for non-users.

17 *Id.* at 274 (internal citations omitted).

18 Use of e-cigarettes also may function as a gateway to the use of conventional
19 cigarettes and other combustible tobacco products, thereby undermining decades of
20 progress in curbing youth smoking. A 2018 report by the National Academies of
21 Science, Engineering and Medicine (NASEM) found “substantial evidence that e-
22 cigarette use increases risk of ever using combustible tobacco cigarettes among

23 _____
24 ²² OSG, HHS, *E-Cigarette Use Among Youth and Young Adults, A Report of
the Surgeon General* (2016), [https://e-](https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf)
cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf.

25 ²³ OSG, HHS, *Office of the Surgeon General, Surgeon General’s Advisory on
E-Cigarette Use Among Youth* (2018), [https://e-](https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf)
cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-
26 use-among-youth-2018.pdf.

27 ²⁴ Jessica L. Barrington-Trimis, et al., *Flavorings in Electronic Cigarettes:
An Unrecognized Respiratory Health Hazard?*, 312 J. Am. Med. Ass’n 2493
28 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4361011/>.

1 youth and young adults.”²⁵ A nationally representative analysis found that from
2 2013 to 2016, youth e-cigarette use was associated with more than four times the
3 odds of trying cigarettes and nearly three times the odds of current cigarette use.
4 The researchers estimated that this translates to over 43,000 current youth cigarette
5 smokers who might not have become smokers without e-cigarettes,²⁶ during a
6 period prior to the explosion of youth e-cigarette use from 2017-2019.

7 Thus, given the fast-spreading epidemic of youth e-cigarette use, caused in
8 large part by the appeal of flavored products, the continued implementation of the
9 Flavors Ordinance is critical to the County’s efforts to protect its young people
10 from the addictive and other harmful effects of e-cigarettes.

11 **B. The Claimed Health Benefits of E-cigarettes Are Unproven.**

12 In seeking a preliminary injunction, plaintiffs cite the possibility that smokers
13 may have transitioned, or wish to transition, from combusted tobacco products like
14 cigarettes to e-cigarettes. Mem. of P. & A. in Support of Plaintiffs’ Motion for
15 Preliminary Injunction, ECF 4, at 3. Plaintiffs cite to no data showing that smokers
16 have returned to combustible cigarettes in any of the many jurisdictions that have
17 banned the sales of flavored e-cigarettes, while allowing tobacco-flavored products,
18 as does the Flavors Ordinance.²⁷ In fact, until the popular e-cigarette Juul was
19 introduced into the market and pushed the market to its flavored products, tobacco-
20 flavored e-cigarettes were the single most widely-used flavor, comprising 30–40%

23 ²⁵ National Academies of Sciences, Engineering, and Medicine (NASEM),
24 *Public Health Consequences of E-cigarettes*, at 10 (2018)
https://www.ncbi.nlm.nih.gov/books/NBK507171/pdf/Bookshelf_NBK507171.pdf.

25 ²⁶ Kaitlin M. Berry, et al., *Association of Electronic Cigarette Use with*
26 *Subsequent Initiation of Tobacco Cigarettes in U.S. Youths*, 2 J. Am. Med. Ass’n
Network Open e187794 (2019),
<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425>.

27 ²⁷ The jurisdictions that have taken action against flavored e-cigarettes are set
28 out in Campaign for Tobacco-Free Kids, *States & Localities That Have Restricted*
the Sale of Flavored Tobacco Products (Aug. 5, 2020),
<https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>.

1 of the retail market.²⁸ Moreover, according to the CDC, most adult e-cigarette users
 2 are dual users, i.e., they continue to smoke cigarettes.²⁹ Dual use, even with cutting
 3 back the number of cigarettes smoked, still elevates smokers' health risks for
 4 conditions like cardiovascular disease.³⁰ Moreover, NASEM found that dual use of
 5 cigarettes and e-cigarettes "is not a proven method for combustible tobacco
 6 cigarette cessation."³¹ The FDA reached the same conclusion, finding that,
 7 "systematic reviews of available evidence indicate that there is currently
 8 insufficient data to draw a conclusion about the efficacy of e-cigarettes as a
 9 cessation device."³² The agency cited studies finding that cigarette smokers who
 10 also used e-cigarettes had statistically significantly worse quit rates than those
 11 cigarette smokers who did not use e-cigarettes.³³ The recent Surgeon General's
 12 report on smoking cessation summarized the existing evidence, concluding that
 13 "there is presently inadequate evidence to conclude that e-cigarettes, in general,

14 ²⁸ Alexa R. Romberg, et al., *Patterns of Nicotine Concentrations in*
 15 *Electronic Cigarettes Sold in the United States, 2013-2018*, 203 *Drug and Alcohol*
 16 *Dependence* 1 (2019),
 17 <https://www.sciencedirect.com/science/article/abs/pii/S0376871619302571?via%3Dihub>.

18 ²⁹ CDC, *QuickStats: Cigarette Smoking Status Among Current Adult E-*
 19 *cigarette Users, by Age Group — National Health Interview Survey, United States,*
 20 *2015*, 65 *Morbidity & Mortality Wkly. Rep.* 1177 (2016),
 21 <https://www.cdc.gov/mmwr/volumes/65/wr/mm6542a7.htm>; *see also* CDC, *About*
 22 *Electronic Cigarettes (E-Cigarettes)* (last visited May 18, 2020),
 23 [https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html#who-is-using-e-cigarettes)
 24 [cigarettes.html#who-is-using-e-cigarettes](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/about-e-cigarettes.html#who-is-using-e-cigarettes).

25 ³⁰ Kjell Bjartveit & Aage Tverdal, *Health Consequences of Smoking 1-4*
 26 *Cigarettes per Day*, 14 *Tobacco Control* 315 (2005),
 27 <https://tobaccocontrol.bmj.com/content/14/5/315>; Allen Hackshaw, et al., *Low*
 28 *cigarette consumption and risk of coronary heart disease and stroke: meta-analysis*
 of 141 cohort studies in 55 study reports, 360 *BMJ* j5855 (2018),
<https://www.bmj.com/content/360/bmj.j5855.long>; OSG, HHS, *The Health*
Consequences of Smoking: A Report of the Surgeon General 361-407 (2004)
https://www.cdc.gov/tobacco/data_statistics/sgr/2004/index.htm.

³¹ NASEM, *supra* note 25, at 617.

³² Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and
 Cosmetic Act, as Amended by the Family Smoking Prevention Tobacco Control
 Act; Restrictions on the Sale and Distribution of Tobacco Products and Required
 Warning Statements for Tobacco Products, 81 *Fed. Reg.* 28,974, 29,037 (May 20,
 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143) ("Deeming Rule").

³³ *Id.* at 29,028, 29,037.

1 increase smoking cessation.”³⁴ The fact is that no e-cigarette has been approved as
2 a smoking cessation drug or device by the FDA.

3 Moreover, plaintiffs offer no evidence that *flavors* in e-cigarettes play any
4 role in smoking cessation. While there may be anecdotal reports of smokers who
5 say flavored e-cigarettes helped them quit, there is no evidence that smokers could
6 not have quit without non-tobacco flavors. There has not been a single randomized
7 controlled trial to assess the impact of flavored versus non-flavored or tobacco-
8 flavored e-cigarettes on smoking cessation outcomes.

9 Therefore, given the entirely unproven benefits of flavored e-cigarettes to
10 smokers, their concrete and well-documented health risks, particularly to youth,
11 weigh heavily against the issuance of an injunction against the Flavors Ordinance.

12 **II. An Injunction Would be Harmful to the Health of County Residents**
13 **by Allowing the Continued Sale of Menthol Cigarettes.**

14 Menthol cigarettes are a substantial threat to public health because they
15 increase the risk of youth initiation of smoking, increase addiction, and
16 disproportionately affect the African American community, thus exacerbating
17 serious health disparities. Because the injunction sought by plaintiffs would expose
18 the residents of San Diego County to the continued health harms of menthol
19 cigarettes, it is decisively contrary to the public interest.

20 **A. Menthol Cigarettes Increase Youth Initiation of Smoking and**
21 **Make it Harder for Smokers to Quit.**

22 Although the tobacco companies know that almost all new tobacco users
23 begin their addiction as kids, they also know that, to novice smokers, tobacco
24 smoke can be harsh and unappealing. By masking the harshness and soothing the
25 irritation caused by tobacco smoke, menthol cigarettes make it easier for beginners
26 to experiment with cigarettes and ultimately become addicted. Thus, young
27 smokers are more likely to use menthol cigarettes than any other age group. Over

28 _____
³⁴ 2020 SG Report, *supra* note 24, at 23.

1 half of youth smokers ages 12-17 use menthol cigarettes, compared to less than
 2 one-third of smokers aged 35 and older.³⁵ As the FDA has observed, “[m]ultiple
 3 studies show a greater use of menthol cigarettes by younger smokers and less usage
 4 among older smokers.”³⁶ The FDA’s Tobacco Products Scientific Advisory
 5 Committee (TPSAC), after an extensive study of the public health impact of
 6 menthol cigarettes, concluded in a 2011 Report that menthol cigarettes increase the
 7 number of children who experiment with cigarettes and the number who become
 8 regular smokers, increasing overall youth smoking, and that young people who
 9 initiate using menthol cigarettes are more likely to become addicted and become
 10 long-term daily smokers.³⁷

11 The impact of menthol cigarettes in attracting kids, and keeping them
 12 addicted, has profoundly adverse effects on their health. The FDA has written that
 13 “smoking cigarettes during adolescence is associated with lasting cognitive and
 14 behavioral impairments, including effects on working memory in smoking teens
 15 and alterations in the prefrontal attentional network in young adult smokers.”³⁸
 16 “Use of tobacco products,” according to the FDA, “puts youth and young adults at
 17 greater risk for future health issues, such as coronary artery disease, cancer, and

18 _____
 19 ³⁵ Andrea Villanti, et al., *Changes in the Prevalence and Correlates of*
 20 *Menthol Cigarette Use in the USA, 2004–2014*, 25 *Tobacco Control* ii14 (2016),
<https://pubmed.ncbi.nlm.nih.gov/27729565/>.

21 ³⁶ Advance Notice of Proposed Rulemaking, *supra* note 5, at 12,296.

22 ³⁷ Tobacco Products Scientific Advisory Committee, FDA, *Menthol*
 23 *Cigarettes and Public Health: Review of the Scientific Evidence and*
 24 *Recommendations* at 136, 199-202 (2011), [https://wayback.archive-](https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf)
 25 [it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/](https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf)
 26 [CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UC](https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf)
 27 [M269697.pdf](https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf) (TPSAC Menthol Report). Plaintiffs’ Memorandum takes out of
 28 context an expression of concern, in a Congressional Report on the Tobacco
 Control Act, that immediately prohibiting a widely-used tobacco product may lead
 to addicted smokers suffering “sudden withdrawal” and other “unknown
 consequences.” Pls.’ Mem. P. & A. 7. Plaintiffs fail to mention that the Act
 mandated TPSAC to study the menthol issue in all its dimensions, TPSAC did a
 thorough study and concluded that “[r]emoval of menthol cigarettes from the
 marketplace would benefit public health in the United States.” TPSAC Menthol
 Report at 225.

³⁸ Advance Notice of Proposed Rulemaking, *supra* note 5, at 12,295.

1 other known tobacco-related diseases. Youth and young adult . . . cigarette smokers
 2 also are at increased risk for future marijuana and illicit drug use, developmental
 3 and mental health disorders, reduced lung growth and impaired function, increased
 4 risk of asthma, and early abdominal aortic atherosclerosis.”³⁹

5 In its 2011 Report, TPSAC projected that by 2020, about 2.3 million people
 6 will have started smoking because of menthol cigarettes, leading to 17,000
 7 premature deaths.⁴⁰ Moreover, there is no question that increased smoking
 8 prevalence due to menthol cigarettes is of heightened concern because of the
 9 COVID-19 pandemic. As Dr. Brian King of the CDC recently warned, “Cigarette
 10 smoking can suppress the immune system and cause heart and lung diseases. A
 11 person who smokes may be at greater risk for, and may have a harder time
 12 recovering from, COVID-19.”⁴¹ The World Health Organization has found that
 13 “smokers are more likely to develop severe disease with COVID-19 compared to
 14 non-smokers.”⁴² Thus, as important to public health as a prohibition of the sale of
 15 menthol cigarettes was before the current pandemic, it is even more vital now.

16 **B. Menthol Cigarettes have led to Significant Health Disparities for**
 17 **African Americans.**

18 In addition to leading millions of youth into tobacco addiction, menthol
 19 cigarettes have played an especially pernicious role in victimizing the African
 20 American community. Dating back to the 1950s, the tobacco industry has targeted
 21 African Americans with marketing for menthol cigarettes through sponsorship of
 22 community and music events, targeted magazine advertising, youthful imagery and
 23 marketing in the retail environment. The 2018 California Tobacco Retail
 24

25 ³⁹ *Id.* at 12,295-96.

26 ⁴⁰ TPSAC Menthol Report, *supra* note 37, at 221.

27 ⁴¹ Brian King, Am. Lung Ass’n, Webinar, *Update with CDC for Chronic Disease Partners on COVID-19*, April 17, 2020.

28 ⁴² World Health Organization, *Tobacco Use and COVID-19* (May 11, 2020),
<https://www.who.int/news-room/detail/11-05-2020-who-statement-tobacco-use-and-covid-19>.

1 Surveillance Study found significantly more menthol advertisements at stores with
 2 a higher proportion of African American residents and in neighborhoods with
 3 higher proportions of school-age youth.⁴³ Another 2011 California study found that,
 4 as the proportion of African American high school students in a neighborhood rose,
 5 the proportion of menthol advertising increased.⁴⁴ As TPSAC concluded, menthol
 6 cigarettes are “disproportionately marketed per capita to African Americans.
 7 African Americans have been the subjects of specifically tailored menthol
 8 marketing strategies and messages.”⁴⁵

9 The tobacco industry’s use of menthol cigarettes to target African Americans
 10 has paid handsome, but tragic, rewards. The prevalence of menthol use *is highest*
 11 *among African Americans – 85% of African American smokers smoke menthol*
 12 *cigarettes, compared to 29% of Whites.*⁴⁶ In its 2011 TPSAC report, the FDA
 13 concluded that menthol cigarettes are associated with lower levels of smoking
 14 cessation among African Americans.⁴⁷ TPSAC also estimated that by 2020, over
 15 460,000 African Americans will have started smoking because of menthol
 16 cigarettes, and 4,700 excess deaths of African Americans will have been
 17 attributable to menthol cigarettes.⁴⁸ Indeed, the public health importance of the
 18 Flavors Ordinance for African Americans is made especially clear by the COVID-
 19 19 pandemic, which has revealed stark health disparities across our nation. A
 20 Washington Post analysis showed that counties that are majority-black have three

21
 22 ⁴³ Nina Schleicher, et al., *California Tobacco Retail Surveillance Study*,
 23 2018, Stanford Prevention Research Center, at 3, 22 (2019),
 24 <https://www.cdph.ca.gov/Programs/CCDC/DCDC/CTCB/CDPH%20Document%20Library/ResearchandEvaluation/Reports/CaliforniaTobaccoRetailSurveillanceStudyReport-2018.pdf>.

25 ⁴⁴ Lisa Henriksen, et al., *Targeted Advertising, Promotion, and Price for*
 26 *Menthol Cigarettes in California High School Neighborhoods*, 14 *Nicotine*
 27 *Tobacco Rsch.* 116 (2012),
 28 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3592564/>.

⁴⁵ TPSAC Menthol Report, *supra* note 37, at 92.

⁴⁶ 2020 SG Report, *supra* note 34.

⁴⁷ TPSAC Menthol Report, *supra* note 37, at 147.

⁴⁸ *Id.* at 206.

1 times the rates of COVID-19 infections and almost six times the rate of deaths as
2 counties where white residents are in the majority.⁴⁹ According to a recent CDC
3 analysis of the effects of COVID-19, “current data suggest a disproportionate
4 burden of illness and death among racial and ethnic minority groups.”⁵⁰ Race and
5 ethnicity data from 580 patients hospitalized with lab-confirmed COVID-19 across
6 14 states, including California, found that 33% of hospitalized patients were black
7 compared to 18% of individuals in the surrounding community.⁵¹

8 Although multiple and complex factors contribute to racial health disparities
9 in the U.S., the disproportionate burden of COVID-19 on the African American
10 community surely underscores the urgency of laws like the Flavors Ordinance,
11 given the disproportionate impact of menthol cigarettes on that community and the
12 likelihood that smokers are particularly vulnerable to the worst effects of the novel
13 coronavirus. The balance of equities, and the public interest, strongly weigh against
14 an injunction against the Flavors Ordinance in the midst of a pandemic of
15 respiratory disease that is having such a deadly and disproportionate effect on the
16 African American community.

17 **III. An Injunction Would Be Harmful to the Health of County Residents**
18 **by Allowing the Continued Sale of Flavored Cigars.**

19 Like other flavored tobacco products, flavored cigar smoking presents
20 substantial health risks – risks that are particularly concerning given the prevalence
21 of cigar use among children and the tobacco industry’s efforts to market cigars to
22 youth. Historically, cigar manufacturers designed flavored cigars to serve as
23 “starter” smokes for youth and young adults because the flavorings helped mask the

24 _____
25 ⁴⁹ Reis Thebault, et al., *The coronavirus is infecting and killing black*
26 *Americans at an alarmingly high rate*, Washington Post (Apr. 7, 2020),
[https://www.washingtonpost.com/nation/2020/04/07/coronavirus-is-infecting-](https://www.washingtonpost.com/nation/2020/04/07/coronavirus-is-infecting-killing-black-americans-an-alarmingly-high-rate-post-analysis-shows/?arc404=true)
[killing-black-americans-an-alarmingly-high-rate-post-analysis-shows/?arc404=true.](https://www.washingtonpost.com/nation/2020/04/07/coronavirus-is-infecting-killing-black-americans-an-alarmingly-high-rate-post-analysis-shows/?arc404=true)

27 ⁵⁰CDC, *COVID-19 in Racial and Ethnic Minority Groups*,
[https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html)
28 [minorities.html.](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html)

⁵¹ *Id.*

1 harshness, making the products easier to smoke.⁵² According to an industry
 2 publication, “While different cigars target a variety of markets, all flavored tobacco
 3 products tend to appeal primarily to younger consumers.”⁵³ The vice president of
 4 one distributor commented, “For a while it felt as if we were operating a Baskin-
 5 Robbins ice cream store” in reference to the huge variety of cigar flavors available
 6 – and, no doubt, an allusion to flavors that would appeal to kids.⁵⁴

7 More than 1,600 children under age 18 try cigar smoking for the first time
 8 every day.⁵⁵ The 2013-14 PATH study found that 71.7% of youth cigar smokers
 9 used a flavored product in the last month.⁵⁶ The 2019 NYTS showed that
 10 approximately 600,000 middle and high school students had used a flavored cigar
 11 in the last 30 days.⁵⁷ As the FDA has found, “[a]ll cigars pose serious negative
 12 health risks.”⁵⁸ In 2010 alone, regular cigar smoking was responsible for
 13 “approximately 9,000 premature deaths or almost 140,000 years of potential life
 14 lost among adults 35 years or older.”⁵⁹ According to the FDA, “[a]ll cigar smokers
 15 have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to
 16 non-tobacco users,” as well as “other adverse health effects, such as “increased risk
 17 of heart and pulmonary disease,” “a marked increase in risk for chronic obstructive
 18 pulmonary disease,” a higher risk of death from COPD, and “a higher risk of fatal
 19 and nonfatal stroke compared to non-smokers.”⁶⁰

20
 21 ⁵² Ganna Kostygina, et al., *Tobacco Industry use of Flavours to Recruit New*
 22 *Users of Little Cigars and Cigarillos*, 25 *Tobacco Control* 66 (2016),
<https://tobaccocontrol.bmj.com/content/25/1/66>.

23 ⁵³ M. Niksic, *Flavored Smokes: Mmmmm...More Profits?*, *Tobacco Retailer*,
 Apr. 2007.

24 ⁵⁴ *Id.*

25 ⁵⁵ SAMHSA, HHS, *2018 National Survey on Drug Use and Health*, Table
 4.10A, Past Year Initiation of Substance Use Among Persons Aged 12 or Older
 Who Initiated Use Prior to Age 18. Cigars are defined as cigars, cigarillos or little
 26 cigars.

⁵⁶ Advance Notice of Proposed Rulemaking, *supra* note 5, at 12,296.

27 ⁵⁷ CDC, *supra* note 6.

28 ⁵⁸ Deeming Rule, *supra* note 32, at 29,020.

⁵⁹ *Id.*

⁶⁰ *Id.*

1 A preliminary injunction that allows the sale of flavored cigars would be
2 plainly contrary to the public interest.

3 **CONCLUSION**

4 For these reasons, the *amici* public health, medical and community
5 organizations urge the Court to deny plaintiffs a preliminary injunction preventing
6 enforcement of the Flavors Ordinance.

7
8 Dated: August 27, 2020

Respectfully submitted,
BYRON RAPHAEL LLP

9
10 *s/ Jordan Raphael*
Jordan Raphael (SBN 252344)
jraphael@byronraphael.com
1055 West 7th Street, Suite 3300
Los Angeles, California 90017
Tel: (213) 291-9800
Fax: (213) 377-5771

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14 Of counsel:
CAMPAIGN FOR TOBACCO-FREE KIDS
Dennis A. Henigan
dhenigan@tobaccofreekids.org
Swati Rawani
srawani@tobaccofreekids.org
1400 I St. NW, Suite 1200
Washington, DC 20005
Tel: (202) 481-9366
Fax: (202) 296-5427

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19 Attorneys for Proposed *Amici Curiae*

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APPENDIX

DESCRIPTION OF AMICI CURIAE

African American Tobacco Control Leadership Council (AATCLC), formed in 2008, is composed of a cadre of dedicated community activists, academics, and researchers. Our work has shaped the national discussion and direction of tobacco control policy, practices, and priorities, especially as they affect the lives of Black Americans, African immigrant populations and ultimately, all smokers. AATCLC has an interest in flavored tobacco restrictions because such restrictions reduce death and disease especially among Black Americans and others who are disproportionately burdened by tobacco.

The American Academy of Pediatrics, California (AAP-CA) is a nonprofit organization incorporated in the state of California. It is comprised of the four AAP California regional chapters statewide, representing more than 5,000 California primary care and subspecialty pediatricians and pediatric residents, including those throughout San Diego County. Our mission is to support and protect the health well-being of infants, children, adolescents, and young adults in California.

The American Cancer Society Cancer Action Network (ACS CAN) is the nation's leading voice advocating for public policies that are helping to defeat cancer. As the advocacy affiliate of the American Cancer Society, ACS CAN works to encourage government officials to make cancer a top priority, including supporting comprehensive tobacco control.

The American Heart Association (AHA) is a voluntary health organization that, since 1924, has been devoted to saving people from heart disease and stroke—the two leading causes of death in the world. AHA teams with millions of volunteers to fund innovative research, fight for stronger public health policies, and provide lifesaving tools and information to prevent and treat these diseases. The Dallas-based association with local offices in all 50 states, as well as in

1 Washington, D.C. and Puerto Rico, is the nation’s oldest and largest voluntary
2 organization dedicated to fighting heart disease and stroke.

3 The American Lung Association is the nation’s oldest voluntary health
4 organization. The American Lung Association has long been active in research,
5 education and public policy advocacy regarding the adverse health effects caused
6 by tobacco use, including supporting eliminating the sale of all flavored tobacco
7 products.

8 The American Medical Association (AMA) is the largest professional
9 association of physicians, residents, and medical students in the United States.
10 Additionally, through state and specialty medical societies and other physician
11 groups seated in its House of Delegates, substantially all physicians, residents, and
12 medical students in the United States are represented in the AMA’s policy-making
13 process. The AMA was founded in 1847 to promote the art and science of medicine
14 and the betterment of public health, and these remain its core purposes. AMA
15 members practice in every medical specialty and in every state, including
16 California.

17 Americans for Nonsmokers’ Rights (ANR) is a national non-profit tobacco
18 control advocacy organization based in Berkeley, California. Since its formation in
19 1976, ANR has been dedicated to protecting nonsmokers’ rights to breathe smoke-
20 free air in enclosed public places and workplaces and to preventing youth addiction
21 to nicotine, including use of e-cigarettes and other flavored tobacco products. ANR
22 represents a national constituency of over 12,000 individuals and organizations
23 concerned about the health risks that tobacco and other nicotine products pose to
24 the health and safety of smokers and nonsmokers alike and committed to reducing
25 and preventing tobacco and e-cigarette use.

26 California School Nurses Organization (CSNO) is the leading force for
27 excellence in school health services CSNO’s mission is to ensure that school nurses
28 optimize student health and enhance learning through a network distinguished by:

1 facilitating grassroots efforts within regional sections; developing and providing
2 professional learning opportunity; fostering the development of leaders; conducting
3 research and using evidence based practice; providing standards of care; and
4 advocating for school health services.

5 The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce
6 tobacco use and its deadly toll in the United States and around the world. The
7 Campaign envisions a future free of the death and disease caused by tobacco, and it
8 works to save lives by advocating for public policies that prevent kids from
9 smoking, help smokers quit and protect everyone from secondhand smoke. The
10 Campaign for Tobacco-Free Kids has an interest in flavored tobacco restrictions in
11 San Diego County because restrictions impact the use of tobacco products by young
12 people.

13 Parents Against Vaping e-cigarettes (PAVe) is a national grassroots
14 organization founded in 2018 by three moms in response to the youth vaping
15 epidemic. The catalyst for PAVe was their discovery in April, 2018 that a JUUL
16 representative had entered their sons' high-school through an outside anti-addiction
17 group, without the school's knowledge, and told the 9th-grade students, without
18 adults present, that JUUL was "totally safe" and would receive FDA approval "any
19 day." (Their Congressional testimony about this incident was cited by FDA as
20 evidence that JUUL had marketed directly to kids.) PAVe's volunteer parent
21 advocates operate in multiple states across the country, including California. PAVe
22 believes that regulatory and legislative change at the state level is key to slowing
23 the explosive growth of teen vaping and protecting teens from the predatory
24 behavior of Big Tobacco.

25 The Public Health Law Center is a public interest legal resource center
26 dedicated to improving health through the power of law and policy, grounded in the
27 belief that everyone deserves to be healthy. Located at the Mitchell Hamline School
28 of Law in Saint Paul, Minnesota, the Center helps local, state, national, tribal, and

1 global leaders promote health by strengthening public policies. For almost twenty
2 years, the Center has worked with public officials and community leaders across the
3 nation to develop, implement, and defend effective public health laws and policies,
4 including those designed to reduce commercial tobacco use, improve the nation's
5 diet, encourage physical activity, protect the nation's public health infrastructure,
6 and promote health equity. The Public Health Law Center's commercial tobacco
7 control program operates as part of a national network of nonprofit legal centers
8 working to protect public health from the devastating consequences of tobacco use.
9 The Center's affiliated legal organizations include: Public Health Advocacy
10 Institute and the Center for Public Health and Tobacco Policy, both at Northeastern
11 University School of Law, Boston, Massachusetts; ChangeLab Solutions, Oakland,
12 California; Legal Resource Center for Tobacco Regulation, Litigation & Advocacy,
13 at University of Maryland Francis King Carey School of Law, Baltimore,
14 Maryland; Smoke-Free Environments Law Project, at the University of Michigan,
15 Ann Arbor, Michigan; and Tobacco Control Policy and Legal Resource Center at
16 New Jersey GASP, Summit, New Jersey.

17 Truth Initiative Foundation, d/b/a Truth Initiative (Truth Initiative) is a
18 501(c)(3) Delaware corporation created in 1999 out of a 1998 master settlement
19 agreement that resolved litigation brought by 46 states, five U.S. territories, and the
20 District of Columbia against the major U.S. cigarette companies. Headquartered in
21 Washington, D.C., Truth Initiative studies and supports programs in the United
22 States to reduce youth smoking, vaping and nicotine use and to prevent diseases
23 associated with tobacco products. Its nationally recognized truth® campaign has
24 educated hundreds of millions of young people about the health effects and social
25 costs of tobacco.